REMARKS

Claims 58–69, as amended, and new claims 70–80 are pending in the application. Claims 36, 56, and 57 are canceled without prejudice. The amendment to claim 58 was made to correct typographical errors. Support for the chemical names is found in the specification on pages 232, 236–240, 292, and 293. New claim 70 is of the exact same scope as previous claim 34. New method claims 71 and 76 find support in the specification on pages 196–197. Dependent claims 72–75 and 77–80 limit claims 71 and 76, respectively, by naming a single compound which is claimed per se in earlier claims and supported in the specification. Therefore, no new matter is added with the amendments or the new claims.

Claims 36, 56, and 57 stand rejected under 35 U.S.C. 112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner alleges that methods describing "disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels" or "cardiovascular disease" are "reach-through claims", do not represent practical utilities and are not patentable under current practice. Applicants respectfully disagree.

Without acquiescing to the rejection, but in order to facilitate prosecution, applicants have canceled claims 36, 56, and 57 and replaced them with new claims 71–80. New claims 71–80 relate to methods of increasing HDL or decreasing LDL in a patient in need thereof comprising the administration of the compounds listed herein. Increasing HDL and decreasing LDL are therapeutically beneficial and are recognized, practical utilities. These utilities are demonstrated, for example, in Tables 6 and 8 of the specification. Applicants point out that each compound listed in claims 71–80 are named in the specification on pages 232, 236–240, 292, and 293. The specification also teaches on pages 196–197 that the compounds of the invention raise HDL and lower LDL. Since the specification clearly teaches the specific compounds and the specific utilities of raising HDL and lowering LDL, applicants clearly had possession of the claimed invention at the filing date.

Therefore, claims 71–80 satisfy the written description requirement under 35 USC 112, first paragraph. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 36, 56, and 57 stand rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement. In applying the Wands factors, the Examiner alleges that the breadth of the claims includes many compounds broadly taught to treat or prevent all cardiovascular diseases or disorders capable of being treated or prevented by increasing HDL or decreasing LDL levels. The Examiner acknowledges that the compounds are useful for treating dyslipidemia but argues that not every instance of lipidemia leads to all known cardiovascular diseases. The Examiner also argues that the specification fails to disclose how normal patients "who are predisposed to these unnamed diseases would be identified and treated before developing the unnamed diseases." Applicants respectfully traverse the rejection.

Without acquiescing to the rejection, applicants cancel claims 36, 56, and 57 and replace them with new claims 71–80. As related above, claims 71–80 relate to methods of increasing HDL or decreasing LDL in a patient in need thereof comprising administering a small group of compounds set forth in claims 71 and 76. The specification clearly sets forth how to make the compounds as set forth in the synthetic examples, for example, on pages 232–240 and in the generic synthetic schemes provided on pages 141–193 of the specification. Further, the specification sets forth how to formulate and administer the compounds on pages 216–222.

Table 8 on page 296 of the specification sets forth the effects of nine of the compounds on nonHDL cholesterol, HDL cholesterol, triglyceride levels, glycemic control indicators and body weight control in Obese Female Zucker Rats. Table 6 on pages 292 and 293 further sets forth the effects of the same nine compounds on lipid synthesis in primary rat hepatocytes. The compounds clearly demonstrate pharmacological effects that represent patentable utility.

Regarding the Examiner's questioning how one would identify appropriate patients, applicants submit that such an action is well within the skill of the ordinary clinician. There are numerous LDL-lowering drugs on the market including several in the statin class such as lovastatin, simvastatin, atorvastatin, rosuvastatin, and the like. Some of these drugs, e.g. rosuvastatin also possess HDL-raising properties. Clinicians are well aware of how to identify appropriate patients for the claimed compounds.

Applicants submit that the specification clearly sets forth how to make and use the claimed invention without undue experimentation. Therefore, the pending claims satisfy the enablement requirement. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 36, 56, and 57 stand rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite. The Examiner does not provide any reasons why the claims are allegedly indefinite, but merely states that the same reasons used for arguing that the claims lack written description support and enablement under 35 U.S.C. 112, first paragraph render the claims indefinite. Applicants respectfully disagree. The standard for indefiniteness is that the claims must be insolubly ambiguous. Claims can lack enablement and perhaps lack written description but still be definite.

Without acquiescing to the rejection, applicants submit that new claims 71–80 are definite. The claims relate to a method of either increasing HDL or reducing LDL (established beneficial pharmacological effects) in a patient in need thereof using a small and discreet group of compounds. Applicants respectfully request that the indefiniteness rejection under 35 U.S.C. 112, second paragraph be reconsidered and withdrawn.

The Examiner has determined that claims 58–69 are allowable over the prior art of record but indicates that applicants must delete any overlap with related U.S. Patents 6,699,910; 7,304,092; 7,119,221; 7,335,689; and 7,335,799. Applicants

confirm that there is no overlap between the pending claims and the claims of any of said patents.

The Examiner also requests that a brief description of the drawings be provided in the specification. Applicants direct the Examiner's attention to page 132, section 3.1 of the specification entitled "Brief Description of the Drawings." Applicants do not believe additional description is necessary.

Claims 58–69, as amended, and new claims 71–80 are patentable. Applicants respectfully request the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorneys for the Applicant via telephone if such communication would expedite this application.

Respectfully submitted,

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